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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,328	10/12/2001	Bernd Aldefeld	DE 000174	9218

7590 02/13/2003

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EXAMINER

SMITH, RUTH S

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,328

Applicant(s)

ALDEFELD ET AL. *CA*

Examiner

Ruth S Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 3737

Drawings

The drawings are objected to because the boxes should be labeled as to the elements that they represent. Reference numerals alone are insufficient. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Reference numeral 16. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because reference to figure 1 at the end of the abstract should be deleted. Correction is required. See MPEP § 608.01(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

Art Unit: 3737

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: Throughout the specification, reference to specific claim numbers should be deleted. On page 5, reference numeral 4 is used to refer both to a microcoil and an image acquisition device. On page 5, line 23, "tableau" is questioned. Appropriate correction is required.

Claim Objections

Claim 15 is objected to because of the following informalities: In claim 15, "computer" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose any computer program with program sections for executing the method as set forth in the claims or for controlling the device as set forth in the claims or the medical instrument.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-9 are vague and indefinite in that the

Art Unit: 3737

claims fail to positively set forth any active steps in the method. In the claims, the use of the term "characterized" renders the claims vague and indefinite. It is unclear as to whether such a term is inclusive or exclusive. In claim 6, the recitation of "notably an intravasucular ultrasound device" renders the claim vague and indefinite. In claim 8, the recitation of "notably an intravasucular MR device" renders the claim vague and indefinite. In claim 10, "the position of the medical instrument" lacks antecedent basis. It is unclear as to whether the localization device is in addition to the localization means. In claim 10, "the end zone" lacks antecedent basis. Claim 10 is vague and indefinite in that it defines structure in terms of an unclaimed element such as the instrument. It is unclear as to how the image acquisition device differs from the imaging means. It is unclear as to what is meant by "for the acquisition at the same time of image information...". Claim 10 is incomplete in that it fails to positively set forth means for providing a survey image. In claim 10, "the relevant position" lacks antecedent basis. In claim 11, "the end zone" lacks antecedent basis. Claim 11 is incomplete in that it fails to positively set forth any structure of a medical instrument and means for providing a survey image. It is unclear as to whether claim 11 includes a display as part of the claimed invention. Claim 12 is vague and indefinite in view of the term "notably a catheter". Furthermore, inasmuch as claim 11 fails to positively set forth any structure of the instrument, it is unclear as to what is flexible. Claim 14 is vague and indefinite in that it is unclear as to what the program steps would consist of. Claim 15 is vague and indefinite in that it is unclear as to how a computer program can include a medical instrument.

Claim Rejections - 35 USC § 101

Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims directed to a computer program are considered to be non-statutory.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3737

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5,9-11,13-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Manwaring et al. The claims are directly readable on Manwaring et al which disclose an apparatus including an endoscope for providing live video images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the endoscope and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. The apparatus includes a computer for carrying out the method of using the apparatus as seen in the flow charts provided. With respect to claim 5, the sensing coils are inherently detectable by a magnetic resonance device or an ultrasound device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al in view of Van Vaals et al. Manwaring et al disclose an apparatus including an medical instrument for providing live video images 44, an imaging means

Art Unit: 3737

for providing and storing survey images 42 and localization means which located the position of the instrument and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. Manwaring et al fails to specifically disclose the use of catheter and a microcoil and MRI system used as a localization means. Van Vaals et al disclose an a catheter having localization means including a microcoil used with a magnetic resonance imaging system to locate the position of the catheter. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the localization means is as disclosed by Van Vaals. Such a modification merely involves the substitution of one known type of localization means. It should be noted with respect to claim 12, that an endoscope is considered to be a type of catheter.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al in view of Slettenmark. Manwaring et al disclose an apparatus including an medical instrument for providing live video images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the instrument and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. Manwaring et al fails to specifically disclose the use of an ultrasound localization means. Manwaring et al disclose that instead of a magnetic localization means an acoustic means can be used. Slettenmark is just one example of many which disclose the use of an ultrasound localization means. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the localization means is an ultrasound localization means. Such a modification merely involves the substitution of one known type of localization means for another.

Claims 6,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al in view of Dickinson et al or Ben-Haim et al. Manwaring et al disclose an apparatus including an medical instrument for providing live video images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the instrument and superimposes such on the survey

Art Unit: 3737

image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. Manwaring et al fails to specifically disclose the use of an intravascular ultrasound device as a means to provide the live video. Ben-Haim et al and Dickinson et al each disclose an intravascular ultrasound catheter which provides images around the tip of the catheter. The catheter further includes means for locating the position of the catheter in the body using a magnetic localization means. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the endoscope is replaced with an intravascular ultrasound imaging catheter. Such a modification merely involves the substitution of one known type of invasive imaging probe for another.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al in view of Ozawa et al. Manwaring et al disclose an apparatus including an endoscope for providing images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the endoscope and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. Manwaring et al fails to specifically disclose the use of an OCT device as a means to provide the video images. Ozawa et al disclose an endoscope which includes an OCT device for providing images inside a patient. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the endoscope used includes an OCT device for providing the live images. Such a modification merely involves the substitution of one known type of invasive imaging probe for another.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al in view of Wendt et al. Manwaring et al disclose an apparatus including an medical instrument for providing images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the instrument and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. Manwaring et al fails to specifically disclose the use of an MR probe as a means to provide the video images.

Art Unit: 3737

Wendt et al disclose an MR probe that can be placed in the body in combination with means outside the body to provide images. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the endoscope is replaced with an MR imaging catheter. Such a modification merely involves the substitution of one known type of invasive imaging probe for another. It should be noted that the placement of the probe in any desired position in the patient would have been obvious to one skilled in the art depending upon where the procedure is to be carried out.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Ruth S Smith
Primary Examiner
Art Unit 3737

RSS
February 6, 2003